

CLAIMS

1. Controlled-release oral pharmaceutical compositions containing as active ingredient 5-amino-salicylic acid, comprising:

- a) an inner lipophilic matrix consisting of substances with melting point below 90°C in which the active ingredient is at least partly inglobated;
- b) an outer hydrophilic matrix in which the lipophilic matrix is dispersed;
- c) optionally other excipients.

2. Compositions as claimed in claim 1, wherein the lipophilic matrix consists of compounds selected from unsaturated and/or hydrogenated fatty acids, salts, esters or amides thereof, fatty acid mono-, di- or triglycerids, waxes, ceramides, cholesterol derivatives.

3. Compositions as claimed in claim 1 or 2, wherein 5-aminosalicylic acid is inglobated in the molten lipophilic matrix by kneading, extrusion and/or granulation.

4. Compositions as claimed in any one of the above claims, wherein the hydrophilic matrix consists of hydrogel-forming compounds.

5. Compositions as claimed in claim 4 wherein the hydrophilic matrix consists of compounds selected from polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrins, pectins, starches and derivatives, alginic acid, natural or synthetic gums.

6. Compositions as claimed in any one of the above claims, comprising a gastro-resistant outer coating.

7. Compositions as claimed in claim 6, wherein the gastro-resistant coating consists of methacrylic acid polymers or cellulose derivatives.

8. Compositions as claimed in any one of the above claims,

12

in the form of tablets, capsules, minitablets, wherein the active ingredient is completely contained inside the lipophilic matrix.

9. Compositions as claimed in any one of claims 1 to 7, in
5 the form of tablets, capsules, minitablets, wherein the active ingredient is dispersed both in the hydrophilic matrix and the lipophilic matrix.

10. Compositions as claimed in any one of the above claims,
wherein the percentage of the active ingredient on the total composition weight ranges from 80 to 95%.

11. A process for the preparation of the compositions of
claims 1-10, which comprises:

- a) melt granulation of at least one portion of the active ingredient with the lipophilic excipients with melting point lower than 90°C;
- b) mixing the granules from step a) with the hydrophilic excipients and subsequent tabletting or compression.

Add a⁴ >